Operational
Excellence Consulting
Empowering Sustainable Change

FMEA

Failure Mode & Effects Analysis

Learning Objectives

Understand what an FMEA is, why it is used, and when can it be deployed

Understand the definitions, scoring system and calculations used in an FMEA

Learn the steps to developing an FMEA and the pitfalls to avoid

History of FMEA

First used in the 1960's in the Aerospace industry during the Apollo missions

In 1974 the USA Navy developed MIL-STD-1629 regarding the use of FMEA

In the late 1970's, USA automotive industry started using it and standardizing it

Outline

1. Introduction to FMEA
2. FMEA Definitions, Scoring System & Calculations
3. FMEA Procedure
4. FMEA Example

Takata Air Bag Recall

TAKATA

Year: 2008 and counting

Cost: $24 billion (2016 estimate)

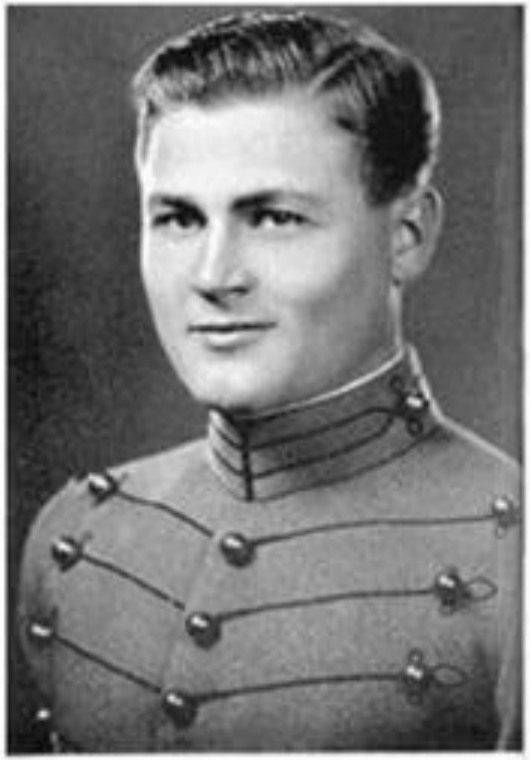
- The largest recall in U.S. auto safety history.
- **The issue:** The inflators can explode and eject a shrapnel-like material that has been linked to at least 20 deaths.

The Space Shuttle Columbia Disaster

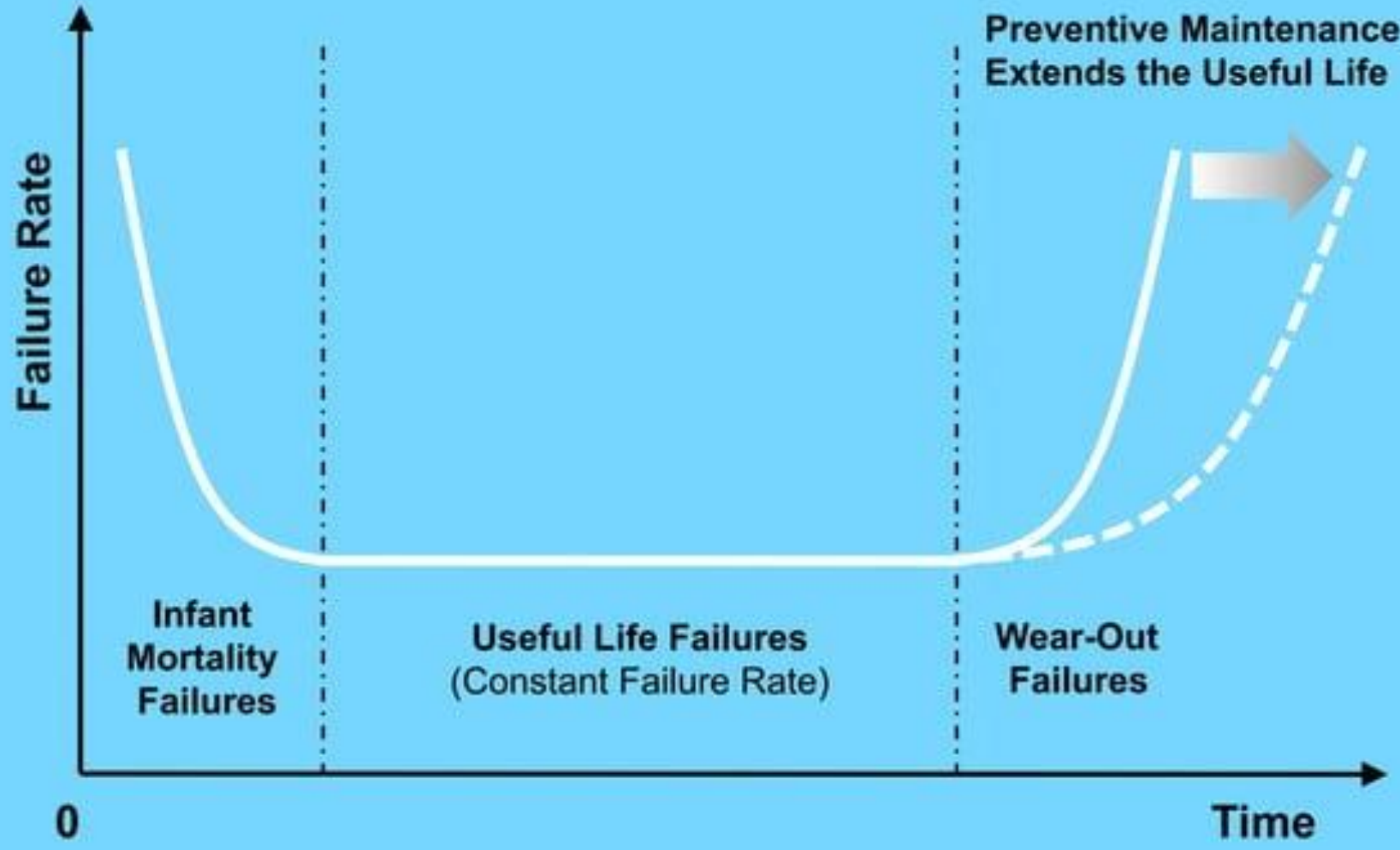
Murphy's Law

"Anything that can go wrong, will go wrong."

Edward A. Murphy, Jr.



The Theory of Preventive Maintenance:
The Bathtub Curve



What is FMEA?

- FMEA stands for Failure Mode & Effects Analysis
- FMEA is a structured approach to:
  - **Identifying the ways in which a product or process can fail**
  - **Estimating risk associated with specific causes**
  - **Prioritizing the actions that should be taken to reduce risk**
  - **Evaluating design validation plan (design FMEA) or current control plan (process FMEA)**

What is an FMEA?

FMEA is a technique for risk assessment prior to release of design, process or service!

It is a cross functional team exercise to list out:

- Potential failure modes
- Causes of these failure modes
- Severity of these failure modes
- Probability (chance) of occurrence
- Probability of detection in the event of occurrence

These three are quantified as numbers between 1 to 10.
Multiplication of the three numbers is ***Risk Priority Number***

DFMEA v. PFMEA

The **DFMEA** or **Design FMEA**, is focused on analyzing and improving the reliability and safety of your *new design*, with a heavy focus on design deficiencies and an analysis of the different interactions, interfaces & product features associated with your new design.

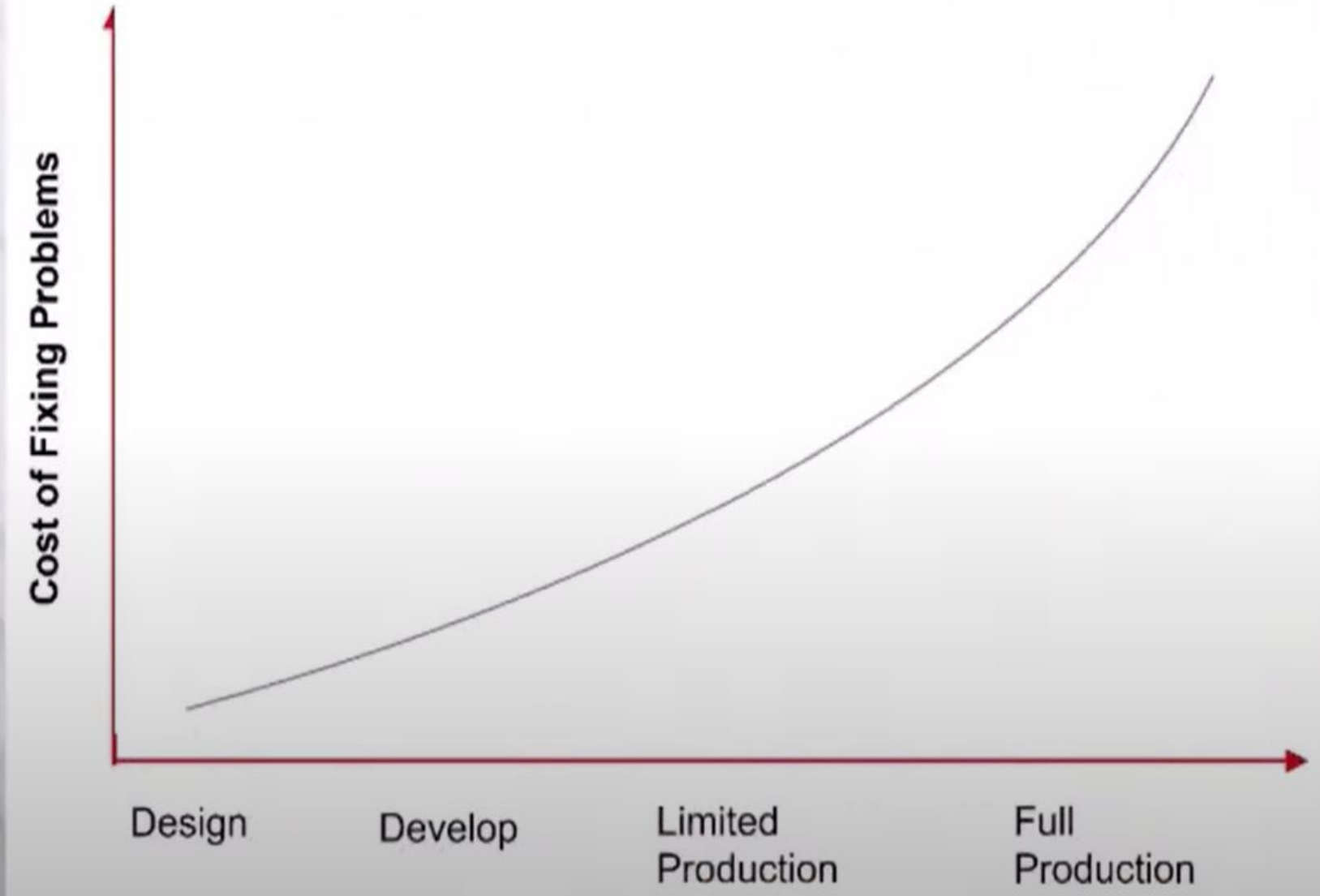
The **PFMEA** or **Process FMEA,** *comes after the DFMEA* and is focused on analyzing your manufacturing or *assembly process* to identify all potential failure modes and then subsequently assess the risk associated with those process deviations.

The 1-10-100 Rule ("Rule of 10")

One dollar spent on prevention will save 10 dollars on correction and 100 dollars on failure costs.

Source: Total Quality Management, Joel E. Ross

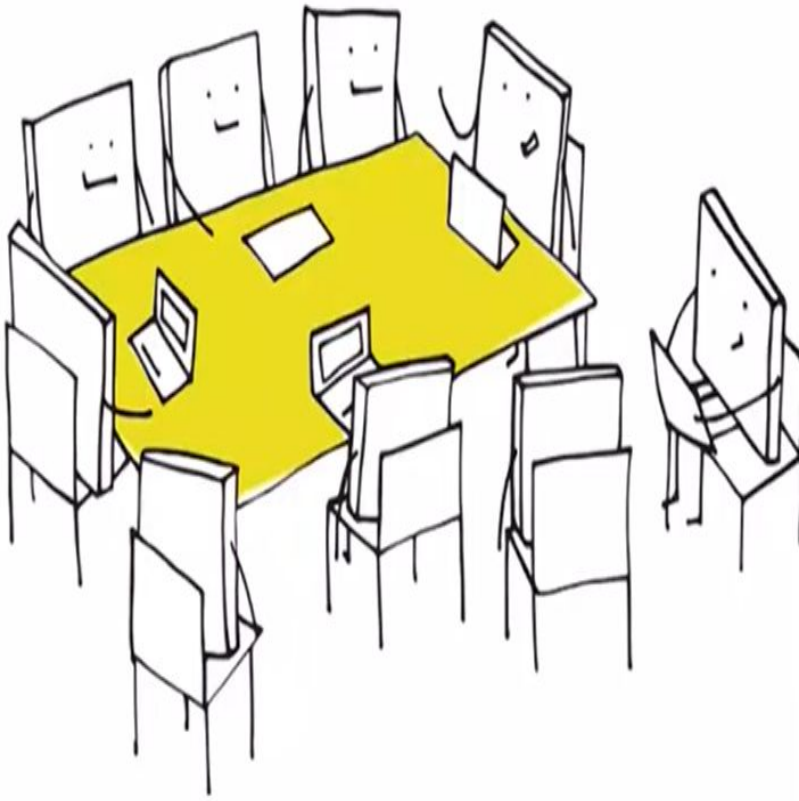
Cost of Fixing Problems increasess multifold as we progress from Design to Production Phase



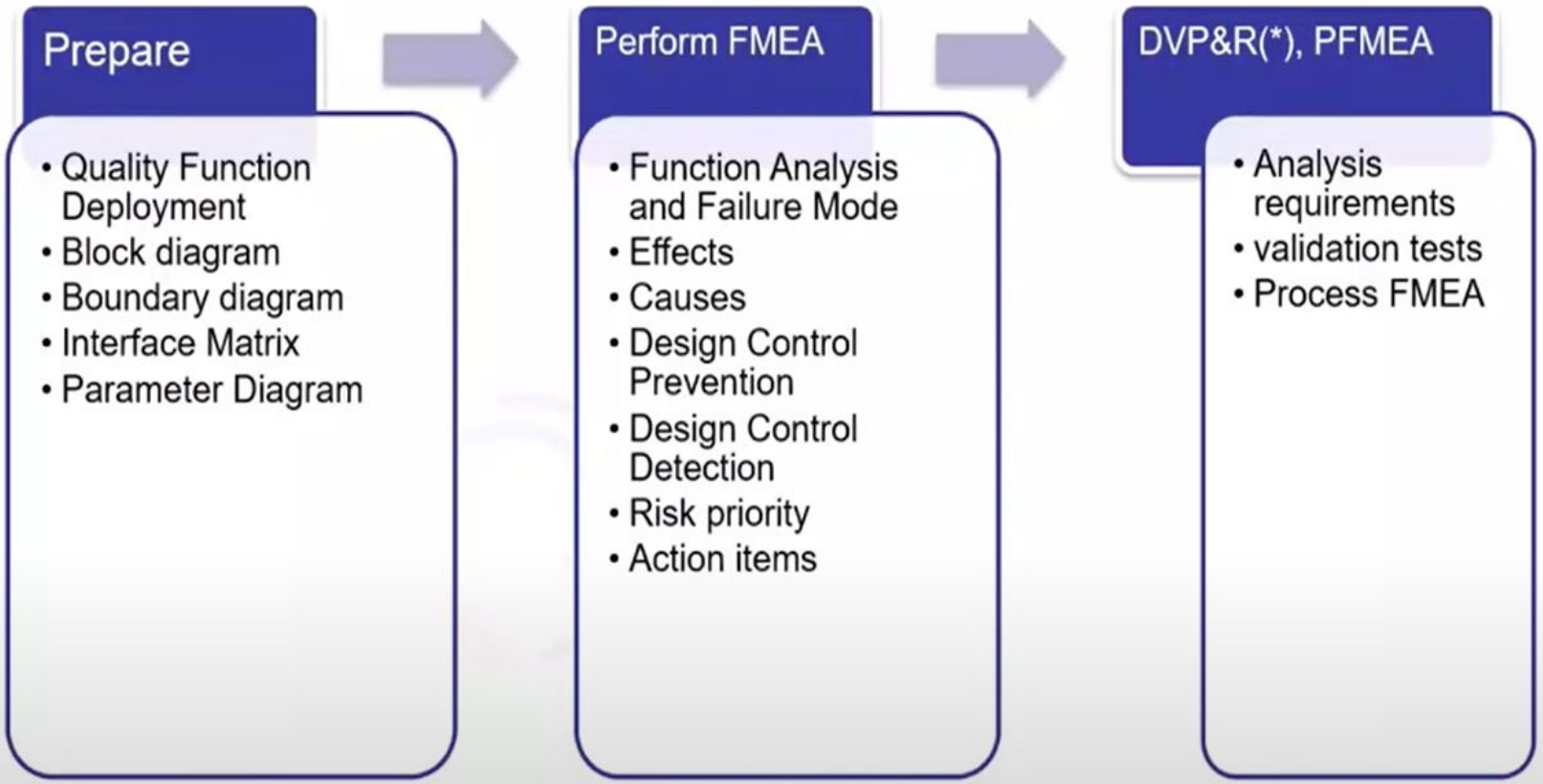
Benefits of FMEA

- Contributes to improved designs for products and processes
  - Higher reliability
  - Better quality
  - Increased safety
  - Enhanced customer satisfaction
  - Contributes to cost savings
  - Decreases development time and re-design costs
  - Decreases warranty costs
  - Decreases waste, non-value added operations
  - Contributes to continuous improvement

- D FMEA is a cross-functional team exercise
- Designers, analysts, quality engineers, service engineers, suppliers' representatives, customer representatives (sometimes) need to participate actively.
- An FMEA is as good as participation with collective knowledge and experience



DFMEA Roadmap



DVP&R: Design Validation Plan and Report

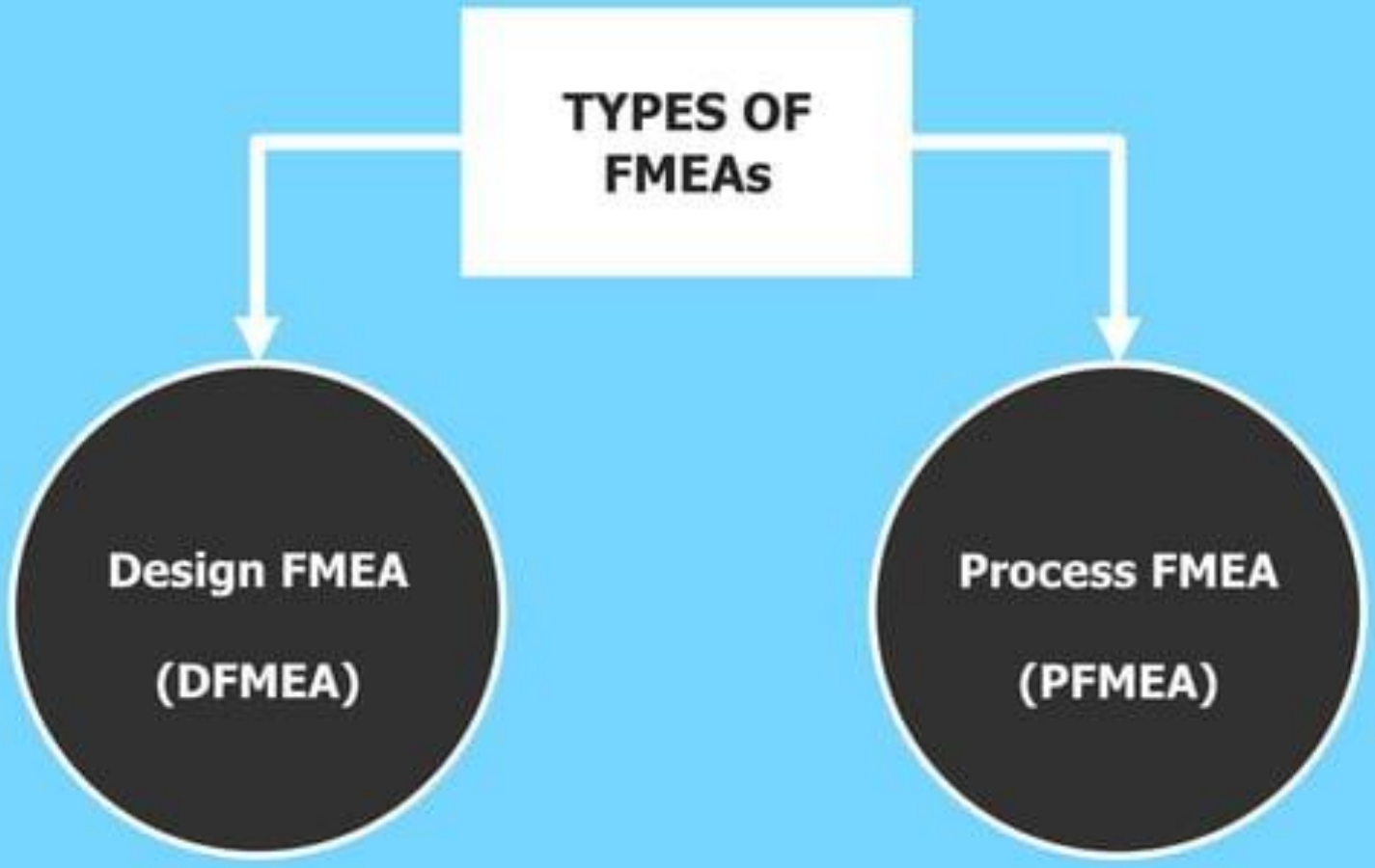
Design FMEA Structure Analysis

System

Subsystem

Component

Types of FMEAs



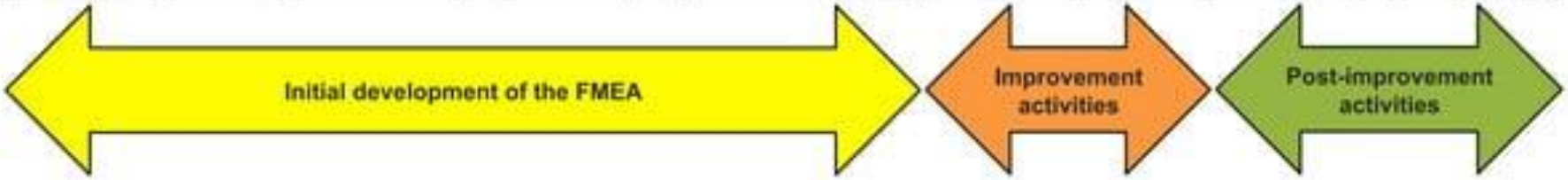
The FMEA Form

Example of a Process FMEA Form

FMEA Form

Process Name:		Prepared by:	Page: of
Process Owner:		FMEA Date (Orig.):	Rev.

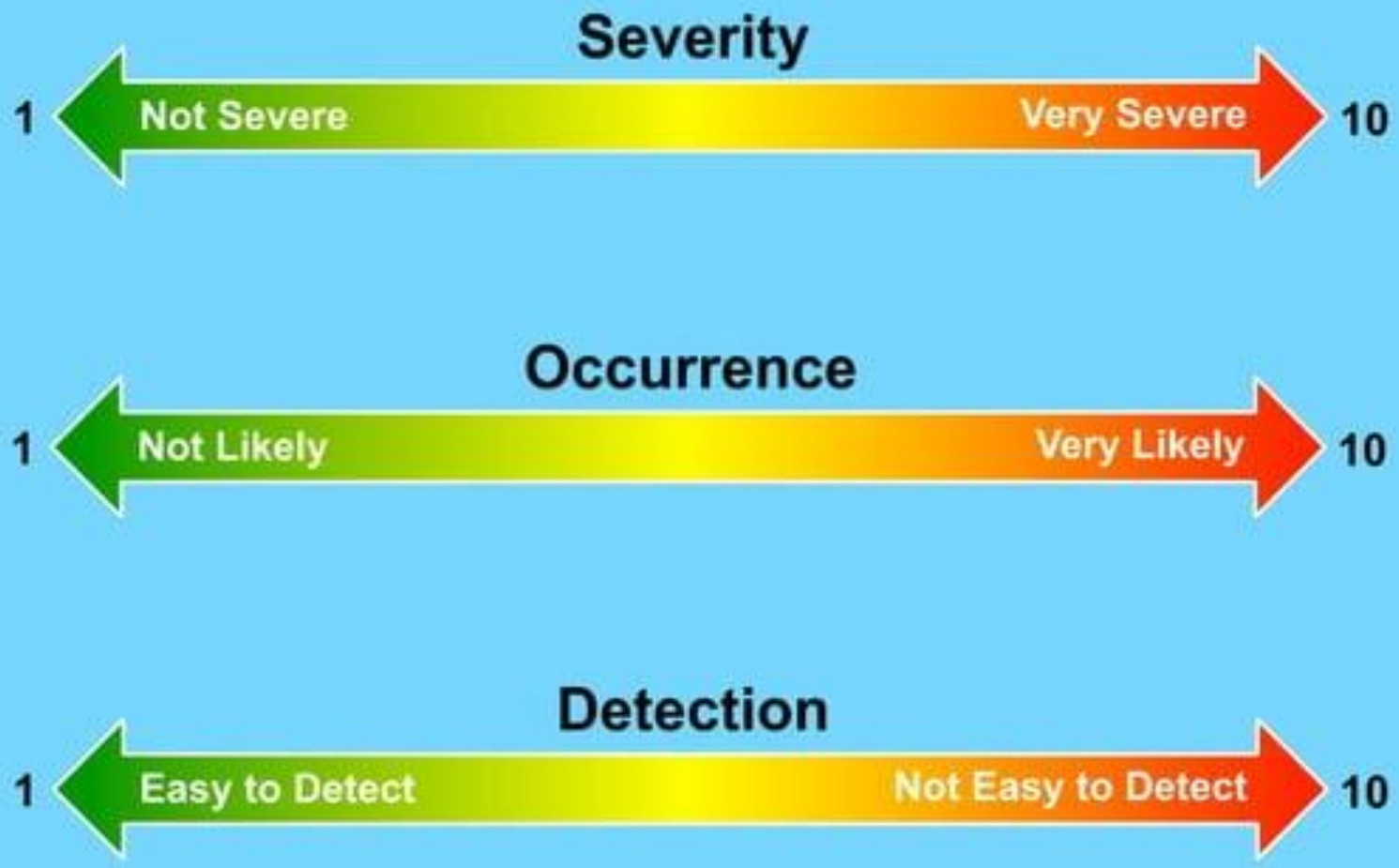
Process Step/ Input	Potential Failure Mode	Potential Failure Effects	SEVERITY (S)	Potential Causes	OCCURRENCE (O)	Current Controls	DECTECTION (D)	RPN	Actions Recommended	Responsibility & Target Completion Date	Actions Taken	SEVERITY	OCCURRENCE	DECTECTION	RPN
What is the process step or key input under investigation?	What can go wrong with the process step or key input?	What is the impact on the customer or key output variables?	How severe is the effect on the customer?	What causes the process step or key input to go wrong?	How often does the cause of the failure mode occur?	What controls and procedures exist that either prevent or detect the cause of the failure mode?	How well can you detect cause or failure mode?	S x O x D	What are the actions for eliminating or reducing the occurrence of the cause, or improving detection of the cause or failure mode?	Who is responsible for the action? When should it be completed?	What are the completed actions taken with the recalculated RPN?				
								0							0
								0							0
								0							0
								0							0
								0							0



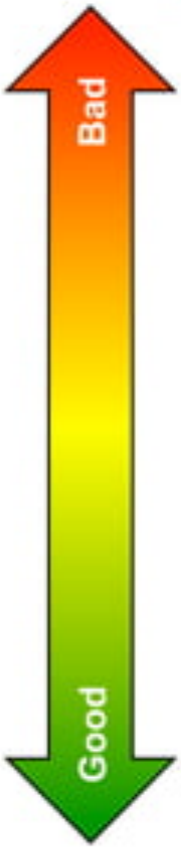
Severity, Occurrence and Detection

Severity	Occurrence	Detection
Importance of the effect on customer requirements.	Frequency with which a given cause occurs and creates failure modes (obtain from past data if possible).	The ability of the current control scheme to detect (then prevent) a given cause (may be difficult to estimate early in process operations).

Scoring System



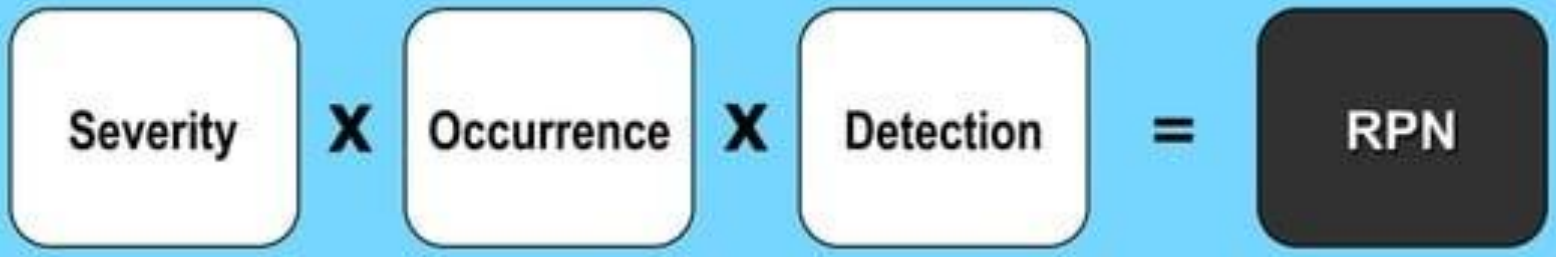
Scoring System – Severity (S)



Score	Severity Guidelines	
	AIAG	Six Sigma
10	Hazardous without warning	Injure a customer or employee
9	Hazardous with warning	Be illegal
8	Very high	Render product or service unfit for use
7	High	Cause extreme customer dissatisfaction
6	Moderate	Result in partial malfunction
5	Low	Cause a loss of performance which is likely to result in a complaint
4	Very low	Cause minor performance loss
3	Minor	Cause a minor nuisance but can be overcome with no performance loss
2	Very minor	Be unnoticed and have only minor effect on performance
1	None	Be unnoticed and not affect the performance

Risk Priority Number (RPN)

RPN is the product of the Severity, Occurrence, and Detection scores.



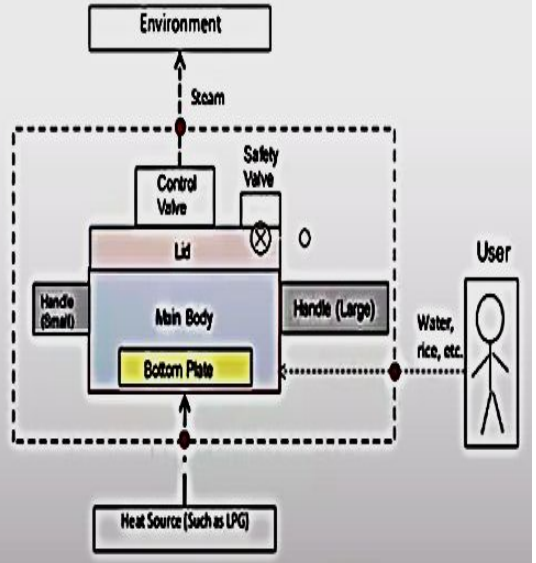
How to Construct an FMEA

1. For each process input (start with high value inputs), determine the ways in which the input can go wrong (failure mode)
2. For each failure mode, determine effects
   - Select a severity level for each effect
3. Identify potential causes of each failure mode
   - Select an occurrence level for each cause
4. List current controls for each cause
   - Select a detection level for each cause

Example of DFMEA

This is an example of DFMEA (partial) for pressure cooker as a system

Item / Function	Requirements	Potential Failure Mode	Potential Effects of Failure	Severity	Class	Potential Causes / Mechanisms of Failure	Current Design Controls Prevention	Occurrence	Current Design Controls Detection	Detect	R.P.N.
Cook fast	10 minutes for 0.5 Kg rice and 0.25 Kg pulses	Steam leak resulting in more time than specified	Excess fuel burn, delay, irritation	7		Rubber ring crush low	Rubber Specs: dimensions and material	4	Cyclic test for rubber ring	7	196
Cook fast	10 minutes for 0.5 Kg rice and 0.25 Kg pulses	Steam leak resulting in more time than specified	Excess fuel burn, delay, irritation	7		Rubber ages	Rubber Specs	7	None	10	490
Cook fast	10 minutes for 0.5 Kg rice and 0.25 Kg pulses	Pressure is lower than desired value resulting in more cooking time	Excess fuel burn, delay, irritation	7		Control valve seat does not seal	Angle and surface quality at control valve	6	Seat angle tolerance	7	294
Release pressure for safe operation	Release pressure When it exceeds 1.3 Kg/cm^2	Safety valve does not break at 1.3 Kg/cm^2	Injury to the person	10	C	Valve mechanism failure due to corrosion	Dimensional and Mechanical Specs	3	None	10	300



Group Workshop

1. Assemble in teams
2. Develop an FMEA for a product or process for ***one*** potential failure mode
3. Write key words on sticky notes
4. Place sticky notes on the FMEA canvas
5. Present your FMEA

30 mins

Reasons Why FMEA Fail

1. One person is assigned to complete the FMEA
2. Not customizing the scoring system with company specific data, so they are meaningful to your company
3. The design or process expert is not included in the FMEA or is allowed to dominate the FMEA team
4. Members of the FMEA team are not trained in the use of FMEA, and become frustrated with the process
5. FMEA team becomes bogged down with minute details of design or process, losing sight of the overall objective

END OF PREVIEW

To download this presentation,
please visit:
www.oeconsulting.com.sg

Operational
Excellence Consulting
Empowering Sustainable Change